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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/506,618

12/07/2004

Steven Melvyn Howdle

P70039US0

4009

136 7590 09/27/2010

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EXAMINER

HELM, CARALYNNE E

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

09/27/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/506,618	<b>Applicant(s)</b> HOWDLE ET AL.	
	<b>Examiner</b> CARALYNNE HELM	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 25,26,28,30-42 and 44-59 is/are pending in the application.
- 4a) Of the above claim(s) 28,30,31,34-36,38,41,44,46,47,50-52,54 and 57-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25,26,32,33,37,39,40,42,45,48,49,53,55 and 56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 13, 2010 has been entered.

### ***Election/Restrictions***

To summarize the current election, applicants elected, with traverse, Group I where the species includes deposition of dissolved/dispersed material by immersion and the deposit material is drugs and pharmaceutical products.

Claims 28, 30-31, 34-36, 38, 41, 44, 46-47, 50-52, 54, and 57-59 were withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 37 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Both claims recite that the method of their parent claim is carried out without blending. The word blend means "to mix into one." Both parent claims explicitly recite method steps that mix multiple components into a composite. Thus it is not clear how the method recited in claims 25 and 42, the parent claims of 37 and 53, can be practiced without blending.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of *Graham v. John Deere Co.* have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 25-26, 33, 39-40, 42, 45, 49, and 55-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lovrecich (EP 0364944) in view of Shim et al. (AICHE Journal 1989 35:1097-1106).

Lovrecich teaches a method of producing a composite of a drug and polymer (see abstract). The method redistributes a drug coated onto a polymer throughout the polymer volume (see page 2 lines 45-47). The method includes a first step of incorporating drug into/onto a polymer, a second step of contacting this polymer with a solvent, and a third step of removing the solvent (see page 2 lines 40-44). Lovrecich teach a first step of incorporating drug into/onto the polymer by immersion of the polymer in a drug solution (see page 3 lines 3-16 and page 5 lines 10-11; instant claims 25, 39, 42, 45, and 55). This immersion necessarily results in drug being coated onto the polymer surface. Subsequently the polymer is dried (see page 3 lines 11 and 16; instant claims 25 and 42). The drying time is envisioned as 12 hours (see page 5 lines

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12-13; instant claims 33 and 49). Lovrecich goes on to teach drug present in/on the polymer at 0.1 parts drug per 100 parts polymer (see page 3 lines 24-25). The drug containing polymer is then exposed to a solvent in liquid or gaseous form, during the second step, which is then separated (released) from the polymer after the desired exposure time (see page 3 lines 42-43; instant claims 25 and 42). The solvent is taught to be any solvent that swells the polymer (see page 4 lines 18-19). In addition, Lovrecich envision estradiol, a steroid drug, as one of the drugs to be loaded into the polymer via their method (see page 4 lines 14 and 16; instant claims 40 and 56). Lovrecich does not explicitly teach a supercritical fluid as the solvent in the second step.

Shim et al. teach that supercritical fluids swell polymers and that this swelling allows for their impregnation with solutes (e.g., drugs) (see page 1097 column 1 paragraph 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to select a supercritical fluid as the solvent in the second step of the method of Lovrecich as the substitution of one known element for another with a predictable outcome. According to MPEP 2144.05IIA, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The amount of drug included in the polymer of Lovrecich in view of Shim et al. is variable based upon the teachings of Lovrecich and

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one of ordinary skill in the art would ultimately select this amount based upon the needs for the end use therapy. Therefore the selection of the claimed drug loading concentration in the polymer would have resulted during the course of routine experimentation by one of ordinary skill in the art at the time of the invention (see instant claims 26 and 42). Therefore claims 25-26, 33, 39-40, 42, 45, 49, and 55-56 are obvious over Lovrecich in view of Shim et al.

Claims 32 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lovrecich in view of Shim et al. as applied to claims 25-26, 33, 39-40, 42, 45, 49, and 55-56 above, and further in view of Mueller et al. (US Patent No. 4,548,990).

Lovrecich in view of Shim et al. make obvious the limitations of instant claims 25 and 42. While Lovrecich envisioned variable immersion times for the polymer in the drug solution in the first step, it does not teach an explicit time for this immersion.

Mueller et al. teach the integration of drug into a polymer by immersion of the polymer in a solution of drug (see column 9 lines 32-35). Specifically, a 12 hour immersion duration is taught (see column 17 lines 24 and 43-46).

As an immersion time that was known to be capable of loading drug into a polymer, it would have been obvious to one of ordinary skill in the art at the time of the invention to select 12 hours for the immersion time in the invention of Lovrecich in view of Shim et al. as the application of a known method to a similar product to produce the same result. Therefore claims 32 and 48 are obvious over Lovrecich in view of Shim et al. and Mueller et al.

***Response to Arguments***

Applicants' arguments, filed January 13, 2010, have been fully considered but they are moot in light of the new grounds of rejection.

The previous rejections are hereby withdrawn in light of the amendment to the claims. New rejections are presented that address the limitations of the claims in their amended form.

***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Friday 9-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/  
Examiner, Art Unit 1615

/Juliet C Switzer/  
Primary Examiner, Art Unit 1634